

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2009 has been entered. Claims 1, 13 and 17 are amended. Claims 2 and 9 are cancelled. Currently claims 1, 3-8, 10-17 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3-8, 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al (USP 4,163,643).

Regarding claims 1 and 17, Hunter et al teach a discrete sample analysis apparatus ("detecting unit") comprising a piezoelectric vibratory conveyer ("transport unit comprises at least one piezoelectric element") (col. 2 lines 18, col. 5 lines 43, col. 12 lines 28-30 and claim 6) to convey samples in a tube ("test element") comprising a collar section 97 ("carrier") and lower section 97 to contain the sample ("evaluation area") to detectors 58 and 59 ("detector") (col. 5 lines 1-10, Fig. 3: 58 and 59). Computing equipment ("evaluation unit") is used to take the measured data and calculate the concentration of the antigen. The transport of the tube is formed to be

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arrested ("stopped") when at detectors 58 and 59 (col. 2 lines 55-60). Hunter et al teach the collar of the tube is in contact with the track ("contact area of the transport unit and the carrier of the test element are made such that in a resting state of the transport unit static frictional forces act between the contact area and the carrier to such an extent that the test element is fixed in position relative to the transport unit") (Fig. 10: M and D).

Regarding claim 3, Hunter et al teach the tubes present in a sample store module 23 ("magazine housing") (col. 7 lines 45-64).

Regarding claim 4, Hunter et al teach the detectors are along the vibratory track (Fig. 3: track near detectors 58 and 59).

Regarding claim 5, Hunter et al teach the piezoelectric drive vibrating the stack of spiral units independently ("at least two piezoelectric elements that are electronically actuated independently of one another") (col. 5 lines 40-48, col. 12 lines 18-31).

Regarding claims 6-8, Hunter et al teach the piezoelectric element is controlled ("detector" is read on controller because it is used "to control") separately by the electrical input from the apparatus ("detection unit") (col. 9 lines 13-27). The same controller ("detector") initiates the detection of the sample in the tube ("detector detects the evaluation area of a test element").

Regarding claim 10, Hunter et al teach a gate mechanism ("contact sensor") which allows for transport ("activates the transport unit") of the tube, which is in contact with the track ("when the test element contacts the contact area of the transport unit").

Regarding claim 11-12, Hunter et al teach the transport unit is arranged on a vertical pillar 118 which allows the spiral units to undergo torsional oscillation

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("rotation"). The pillar is fully capable for bearing and positioning a reel and a test strip tape wound onto a reel.

Regarding claim 13-14, and 16, Hunter et al teach a method for transporting a tube ("test element") in an analytical system comprising contacting a tube ("test element") directly with a contact area of a vibratory piezoelectric transport unit in an analytical system, and prior thereto activating a piezoelectric element of the transport unit such that the contact area of the transport unit is vibrated, transporting the test element due to the vibrated contact area along a predetermined transport path in the analytical system and stopping the transport process of the tube ("test element") such that the test element is positioned at detectors 58 and 59 ("predetermined site in the analytical system" "detection site" "detection unit for detecting at least one signal changed by an analyte") (col. 12 lines 18-31). The computing equipment ("evaluation unit") is used to take the measured data and calculate the concentration of the antigen ("determine at least one analyte in the sample based on the at least one signal")

Regarding claim 15, Hunter et al teach the tube is placed in a storage module 23 ("test element is returned into a magazine").

4. Claims 1, 3-8, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishizaka et al (USP 5,077,010) in view of Kitamoto et al (USP 4,875,610).

Regarding claim 1, 13-14, 16-17, Ishizaka et al teach biochemical analysis apparatus and method ("analytical system for determining an analyte in a sample") comprising providing a measuring device for measuring the optical density produced by a color reaction of a long test film 3 ("a detection unit for detecting at least one signal

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that has been changed by an analyte in a sample”) and the measurement results are fed to a computer 20 (“evaluation unit to determine at least one analyte in the sample based on the at least one signal”) and a motor to rotate a drive a reel of the long test film (“transport unit with a contact area wherein the contact area is suitable for directly or indirectly contacting the analytical system with a test element on which the sample can be applied” “for transporting a test element in an analytical system comprising contacting a test element directly or indirectly with a contact area of a transport unit in an analytical system”). The test film (“test element”) is transported along a defined transport path in the analytical system as soon as the contact area of the transport unit is directly or indirectly contacted with a test element. The test film is mounted on a cassette like those used in audio and video cassette tapes (col. 22 lines 42-51, col. 35 lines 35-54). Ishizaka teach the method further comprising sample application, incubation, and measurement is carried out at a single position (“stopping of the transport process of the test element such that the test element is positioned at a predetermined site in the analytical system” “positioned relative to a detection site of a detection unit of the analytical system”) (col. 11 line 56-col. 12 line 9).

Ishizaka et al is silent that the transport unit comprises at least one piezoelectric element which vibrates the contact area of the transport unit.

Kitamoto et al teach a method and system for driving tape in a cassette comprising a piezoelectric elements 1 and 2 to produce an ultrasonic oscillations to advance the tape (“activating a piezoelectric element of the transport unit such that the contact area of the transport unit is vibrated, transporting the test element due to the

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vibrated contact area along a predetermined transport path in the analytical system”). It is advantageous to use this driving system in order to overcome the tape meandering, twisting or being stretched by tension of the conventional capstan and pinch roller.

It would have been obvious to one of ordinary skill in the art to substitute the motor of Ishizaka et al with the piezoelectric elements of Kitamoto et al in order to provide a driving means that advances the tape without meandering, twisting or being stretched by tension caused by conventional rotating motors.

Regarding claim 2, Ishizaka/Kitamoto teach a test film 210 with a support 211 and an analysis region 214 (“the test element wherein the test element comprises a carrier and an evaluation area on which the sample is applied”).

Regarding claim 3, Ishizaka/Kitamoto teach the test film is in a cassette 1 (“test element is present in a magazine housing”).

Regarding claim 4, Ishizaka/Kitamoto teach a detection site is located in the analytical system along the transport path (Fig. 4: 57).

Regarding claim 5, Ishizaka/Kitamoto teach two piezoelectric elements 1 and 2 can comprise a piezoelectric element pairs, each pair comprising first and second piezoelectric elements 11 and 12. These elements alternate with each other from alternating electric sources Ea and Eb (“that are electronically actuated independently of one another”) in order to create a traveling wave (Kitamoto: col. 2 line 57-col. 3 line 9).

Regarding claim 6 and 10, Ishizaka/Kitamoto teach in which the driving means such as the piezoelectric element is controlled by a tape position detecting means (“detector” “contact sensor which activates the transport unit when the test element

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contacts the contact area of the transport unit”); (Ishizaka: Fig. 4: 56 “photoelectric switch”, col. 12 lines 9-39; Kitamoto: col. 4 line 59-col. 5 line 6).

Regarding claim 7, Ishizaka/Kitamoto teach the detector is a component of the detection unit (Fig. 4: 55-57).

Regarding claim 8, Ishizaka/Kitamoto teach the detector detects holes or markings on the evaluation area of a test film (“element”) (Ishizaka: col. 12 lines 9-39).

Regarding claim 9, Ishizaka/Kitamoto teach the contact area of the piezoelectric elements (“transport unit”) and the test film support (“carrier of the test element”) are made such that in a resting state of the transport unit static frictional forces act between the contact area and the carrier to such an extent that the test element is fixed in position relative to the transport unit.

Regarding claim 11, Ishizaka/Kitamoto teach a reel 6 is mounted on a rotatable shaft (“a carrier element to rotate” “which is suitable for bearing and positioning a reel”). The shaft is fully capable of being rotated by the piezoelectric elements because the tape would be advanced causing the reel to rotate and thus the shaft to rotate.

Regarding claim 12, Ishizaka/Kitamoto teach the use of long test film on a reel (“which is suitable for using a test strip tape wound onto the reel”).

Regarding claim 15, Ishizaka/Kitamoto teach the step wherein the test film (“element”) is returned into a used film cassette part 2 (“test element is returned into a magazine”).

Response to Arguments

5. Applicant's arguments filed on 10/19/2009 have been fully considered but they are not persuasive.
6. Applicants argue that Hunter does not teach the analytical system where static frictional forces act between the contact area of a transport unit and the carrier of a test element to such an extent that the test element is fixed in position relative to the transport unit. Applicants point to Fig. 10 as rationale for this that the barrier and clamping mechanism hold the tube M to cause a queue of sample tubes to form. It is noted that the claim language is open ("comprising") which does not exclude the possibility of other elements acting to hold the test carrier in position. Furthermore, static frictional forces are acting in the Hunter reference; therefore the claim limitations are met.
7. Applicants argue that the Ishizaka and Kitamoto references do not teach the analytical system where static frictional forces act between the contact area of a transport unit and the carrier of a test element to such an extent that the test element is fixed in position relative to the transport unit. It is noted when the device is turned off, static frictional forces are acting in the Ishizaka/Kitamoto device; therefore the claim limitations are met.
8. Applicants might consider a proper and timely submission (e.g. amendments after-final are not proper and timely submissions) of claim amendments that better define the piezoelectric elements.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/LYLE A ALEXANDER/
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